



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

I-009332-P-0090-OT

U.S. Department of Interior  
• Fish and Wildlife Service  
Aquatic Animal Drug Approval Partnership Program  
Attention: Dr. David Erdahl  
4050 Bridger Canyon Road  
Bozeman, MT 59715

MAR 15 2007

Subject: Microbial Food Safety Assessment

Conclusion: Microbial food safety assessment acceptable, Human Food Safety *Technical Section* incomplete.

Dear Dr. Erdahl:

In a letter dated July 18, 2006 (under INAD 009-332), you submitted a "Safety assessment of the microbiological effects on bacteria of human concern for oxytetracycline type A medicated feed." Your submission followed recommendations outlined in the Agency's Guidance for Industry #152, *Evaluating the safety of antimicrobial new animal drugs with regard to their microbiological effects of human health concern*. We have completed our review of your submitted *hazard characterization*.

In your submission, you proposed that the assessment under INAD 009-332 be a component of the Human Food Safety *Technical Section* for a prospective supplement to NADA 038-0439. You stated that the forthcoming supplement to NADA 038-439 would only change claims associated with salmonids and would not amend the catfish claims. Specifically, you seek to include the following two new claims: 1) control of coldwater disease, in all freshwater reared salmonids, caused by *Flavobacterium psychrophilum*, and 2) control of systemic columnaris disease, in steelhead trout *Oncorhynchus mykiss*, caused by *Flavobacterium columnare*.

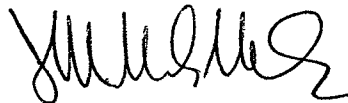
Based on the information in your submission and your referenced data on the intestinal tract microflora contents derived from specific studies in salmonids, the Division of Human Food Safety made a qualitative risk assessment evaluation that integrated information relevant to the conditions of therapeutic use, possible human exposure to the food commodity derived from aquatic species, and the current human drug ranking status of the product. We consider the Microbial Food Safety portion of the Human Food Safety *Technical Section* to be acceptable for the purpose of recommending approval of the proposed forthcoming supplement to the current New Animal Drug Application 038-439. Please be advised that this acceptable microbial food safety finding for the supplement to approved oxytetracycline is limited to salmonids under NADA 038-439, and may not be acceptable for any other aquatic species under NADA 038-439, or acceptable for future supplements to NADA 038-439. This acceptable microbial food safety finding for the supplement to approved

and may not be acceptable for any other aquatic species under NADA 038-439, or acceptable for future supplements to NADA 038-439. This acceptable microbial food safety finding for the supplement to approved oxytetracycline, limited to salmonids under NADA 038-439, assumes that there are no changes in the formulation, dose, duration, route of administration, target animal, or other conditions of use that may impact the assessment of the microbial food safety of this product.

Other Human Food Safety components may need to be addressed prior to issuance of a Human Food Safety *Technical Section Complete* letter. At the time you have addressed all other Human Food Safety concerns for the proposed supplement to NADA 038-439, you should request a Human Food Safety *Technical Section Complete* letter.

In future correspondence, please discuss only one submission per letter. We suggest including the following information in a subject line before the salutation of your letter: the date of this letter, our identifier, I-009332-P-0090, and a brief summary of your request. Please submit your correspondence directly to the Document Control Unit (HFV-199), marked to my attention. If you have questions, please contact Dr. Steve Yan, Acting Team Leader, Microbial Food Safety Team (HFV-157), at 301-827-6463.

Sincerely,



Jeffrey M. Gilbert, Ph.D.  
Acting Director, Division of Human Food  
Safety  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine